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**PATENT**

Attorney Docket No.: 34470/US/3/RFT/SKS

Attorney File No.: 459258-00003

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

*In re* application of:

GALLOP

Serial No. 10/734,689

Filing Date: December 11, 2003

For: *Prodrugs of Fused GABA Analogs,  
Pharmaceutical Compositions and  
Uses Thereof*

Examiner: Not Assigned

Art Unit: 1614

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence, including listed enclosures, is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450:

Dated: March 22, 2005

Signed: [Signature]  
Luke Szymanski

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants wish to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying form PTO/SB/8A. In accordance with 1287 Off. Gaz. Pat. Office 163, 10/19/2004, no copies of U.S. patents and U.S. published applications are enclosed. Copies of all other references are enclosed.

None of the foregoing references are believed to disclose the invention as claimed. Nothing herein shall constitute an admission concerning the contents of any of the cited references, nor shall the inclusion of a reference herein be considered an admission that the reference constitutes prior art against the invention claimed in the above-identified application.

Serial No. 10/734,689

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Submission of the present document shall not be construed as an admission that a search has been made or that better art does not exist.

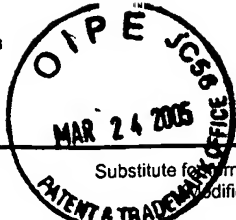
As far as is known to the undersigned, this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits as set forth in 37 C.F.R. § 1.97(b), and therefore no fee is required. While no additional fee is believed to be due, if this belief is in error the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment to Deposit Account No. 50-2319 (Our Order No. 459258-00003 [34470/US/3/RFT/SKS]).

Respectfully submitted,  
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Attachments : Form PTO/SB/8A, Substitute for form 1449  
38 Cited References  
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Substitute for Form 1449A/PTO  
(modified)  
**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

Application Number	10/734,689
Filing Date	December 11, 2003
First Named Inventor	Mark A. Gallop
Art Unit	1614
Examiner Name	Not Assigned
Attorney Docket Number	34470/US/3/AMP/SKS (459258-00003)

Sheet 1 of 3

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No.	U.S. Patent Document Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	3,845,770	11-05-1974	Theeuwes <i>et al.</i>	
	A2	3,916,899	11-04-1975	Theeuwes <i>et al.</i>	
	A3	4,024,175	05-17-1977	Satzinger <i>et al.</i>	
	A4	4,087,544	05-02-1978	Satzinger <i>et al.</i>	
	A5	5,084,169	01-28-1992	Woodruff	
	A6	5,112,598	05-02-1992	Biesalski	
	A7	5,556,611	09-17-1996	Biesalski	
	A8	5,563,175	10-08-1996	Silverman <i>et al.</i>	
	A9	5,698,155	12-16-1997	Grosswald <i>et al.</i>	
	A10	6,001,876	12-14-1999	Singh	
	A11	6,020,370	02-01-2000	Horwell <i>et al.</i>	
	A12	6,028,214	02-22-2000	Silverman <i>et al.</i>	
	A13	6,103,932	08-15-2000	Horwell <i>et al.</i>	
	A14	6,117,906	09-12-2000	Silverman <i>et al.</i>	
	A15	6,596,900	07-22-2003	Blakemore <i>et al.</i>	
	A16	10/171,485		Gallop <i>et al.</i>	
	A17	10/170,127		Cundy <i>et al.</i>	
	A18	10/167,797		Gallop <i>et al.</i>	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Foreign Patent Document Country Code <sup>2</sup> Number <sup>3</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	B1	WO 92/09560 A1	06-11-1992	Silverman,		
	B2	WO 93/23383 A1	11-25-1993	Silverman <i>et al.</i>		
	B3	WO 97/29101 A1	08-14-1997	Horwell <i>et al.</i>		
	B4	WO 97/33858 A1	09-18-1997	Horwell <i>et al.</i>		
	B5	WO 97/33859 A1	09-18-1997	Horwell <i>et al.</i>		
	B6	WO 98/17627 A1	04-30-1998	Bryans <i>et al.</i>		
	B7	WO 99/08671 A1	02-25-1999	Guglietta <i>et al.</i>		
	B8	WO 99/21824 A1	05-06-1999	Bryans <i>et al.</i>		

Examiner Signature	Date Considered
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the complete application form to the USPTO. Time will vary depending on the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449A/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	10/734,689
				Filing Date	December 11, 2003
				First Named Inventor	Mark A. Gallop
				Group Art Unit	1614
				Examiner Name	Not Assigned
Sheet	2	of	3	Attorney Docket Number	34470/US/3/RFT/SKS (459258-00003)

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	B9	WO 99/31057 A1	06-24-1999	Bryans <i>et al.</i>		
	B10	WO 99/31074 A2/A3	06-24-1999	Belliotti <i>et al.</i>		
	B11	WO 99/31075 A1	06-24-1999	Bryans <i>et al.</i>		
	B12	WO 99/37296 A1	07-29-1999	Magnus-Miller <i>et al.</i>		
	B13	WO 99/61424 A1	12-02-1999	Bryans <i>et al.</i>		
	B14	WO 00/31020 A1	06-02-2000	Bryans		
	B15	WO 00/23067 A1	04-27-2000	Pande		
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	B17	WO 01/28978 A1	04-26-2001	Bryans <i>et al.</i>		
	B18	WO 02/00209 A2/A3	01-03-2002	Bryans <i>et al.</i>		
	B19	WO 00/15611 A1	03-23-2002	Bryans <i>et al.</i>		
	B20	WO 02/085839 A1	10-31-2002	Blakemore <i>et al.</i>		
	B21	WO 02/090318 A1	11-14-2002	Blakemore <i>et al.</i>		

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T <sup>6</sup>
	C1	Alderman, "A Review of Cellulose Ethers in Hydrophilic Matrices or Oral controlled-Release Dosage Forms," <i>Int. J. Pharm. Tech. &amp; Prod. Mfr.</i> 1984, 5(3) 1-9.				
	C2	Bamba <i>et al.</i> , "Release Mechanisms in Gelforming Sustained Release Preparations," <i>Int. J. Pharm.</i> 1979, 2, 307.				
	C3	Bryans <i>et al.</i> , "3-Substituted GABA Analogs with Central Nervous System Activity: A Review," <i>Med. Res. Rev.</i> 1999, 19, 149-177				
	C4	During <i>et al.</i> , "Controlled release of dopamine from a polymeric brain implant: in vivo characterization," 1989, <i>Ann. Neurol.</i> 25:351.				
	C5	Goodson, "Medical Applications of Controlled Release," vol. 2, pp. 115-138 (1984).				
	C6	Howard <i>et al.</i> , "Intercerebral Drug Delivery in Rats with Lesion-Induced Memory Deficits," 1989, <i>J. Neurosurg.</i> 71:105-112.				
	C7	Jezyk <i>et al.</i> , "Transport of Pregabalin in Rat Intestine and Caco-2 Monolayers," <i>Pharm. Res.</i> 1999, 16, 519-526.				

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	C8	Langer <i>et al.</i> , "Chemical and Physical Structure of Polymers as Carriers for Controlled Release of Bioactive Agents: A Review," <i>J Macromol. Sci. Rev. Macromol Chem.</i> 1983, 23:61.	
	C9	Langer, "New Method of Drug Delivery," 1990, <i>Science</i> 249:1527-1533.	
	C10	Levy <i>et al.</i> , "Inhibition of Calcification of Bioprosthetic Heart Valves by Local Controlled-Release Diphosphonate," <i>Science</i> 1985 228: 190-192.	
	C11	Magnus, "Nonepileptic Uses of Gabapentin," <i>Epilepsia</i> , (40) (Suppl. 6): S66-S72 (1999).	
	C12	Saudek <i>et al.</i> , "A Preliminary Trial of the Programmable Implantable Medication System for Insulin Delivery," <i>N. Engl. J. Med.</i> , 1989, 321: 574.	
	C13	Sefton, "Implantable Pumps," <i>CRC Crit Ref Biomed. Eng.</i> 1987, 14:201.	
	C14	Verma <i>et al.</i> , "Osmotically Controlled Oral Drug Delivery," <i>Drug Dev. Ind. Pharm.</i> , 2000, 26:695-708.	

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